

REMARKS

Applicants further submit new, current evidence that the problems of underutilization and compliance in the treatment of cardiovascular disease still exist in the medical field. Exhibit 5, submitted herewith, is a recent article by Elizabeth A. McGlynn et al. entitled "The Quality of Health Care Delivered to Adults in the United States," New England Journal of Medicine, Vol. 348, June 26, 2003, pages 2635-2645. This recent study documents poor adherence to many recommended care practices. For example, participants did not get 32 percent of the appropriate care for coronary artery disease (such as beta-blockers or aspirin after myocardial infarction). The study concludes that it identifies serious threats to the health of the American public in adherence to recommended processes for basic care and that strategies to reduce these deficits in care are warranted.

Exhibit 6, submitted herewith, is an editorial by Earl PI Steinberg, M.D., M.P.P., entitled "Improving the Quality of Care – Can We Practice What We Preach?," New England Journal of Medicine, Vol. 348, June 26, 2003, pages 2681-2683. In this editorial, the author questions what it will take to do better. The author lists four actions. First, quality of care should be measured and reported routinely at both the national and provider-specific levels. Second, greater use of information technology must be made. Third, in addition to capitalizing on the power of computers, the profession should draw on the power of patients to improve the quality of care they receive and their health outcomes. Fourth, current financial incentives that often discourage quality improvement must be addressed. Interestingly, Steinberg offers a number of solutions to improve health care delivery; making treatments more

convenient is not one of them.

Exhibit 7, submitted herewith, is an article by Anthony Rodgers entitled "A cure for cardiovascular disease?" British Medical Journal, Vol. 326, June 28, 2003, pages 1407-1408. This article refers to a paper in the same issue of the BMJ about a combination treatment pill for cardiovascular disease. The pill is called the Polypill and it has several components including beta-blockers, lipid lowering agents, aspirin, etc.

The three new Exhibits provide further evidence that the solutions to problems with compliance and under-utilization of helpful medications for cardiovascular treatments are elusive, and have troubled the healthcare industry for a long time, even to this day. The industry continues to struggle to find answers to these perplexing questions.

Respectfully submitted,



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